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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,444	07/11/2003	Julie K. Andersen	314-300710US	4209

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QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C.
P O BOX 458
ALAMEDA, CA 94501

EXAMINER	
KOLKER, DANIEL E	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 09/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/618,444	ANDERSEN, JULIE K.	
	Examiner	Art Unit	
	Daniel Kolker	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19,20,22,23,30-38 and 46-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19,20,22,23,30-38 and 46-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *19-20,22-23,30-38,46-50* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendments and remarks filed 10 July 2006 have been entered. Claims 1 – 18, 21, 24 – 29, 39 – 45, and 51 – 93 have been canceled. Claims 19 – 20, 22 – 23, 30 – 38, and 46 – 50 are pending.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Rejections and Objections

3. The following objections and rejections made in the previous office action are withdrawn:

A. Any objection or rejection over a canceled claim is moot.

B. The objection to claims 23 and 38 for reciting non-elected species is withdrawn in light of the arguments.

C. The rejection under 35 USC 112, first paragraph for lack of enablement commensurate in scope with the claims is withdrawn in light of the amendments.

D. The rejection under 35 USC 112, first paragraph for lack of adequate written description is withdrawn in light of the amendments.

E. The rejection of claims 19 – 20, 22 – 23, 32 – 38, and 48 – 50 under 35 USC 102 as being anticipated by Ben-Shachar is withdrawn in light of the amendment. The claims now require that the agent be administered to a subject having the disease. The prior art teaches first administering the agent, then administering the toxin 6-OHDA to induce the disease. While the prior art teaches protection of the subject against the disease, it does not teach administration of the agent to a patient that already has the disease. However, see the rejection, necessitated by amendment, under 35 USC 103(a).

Maintained Rejections

Claim Rejections - 35 USC § 102

4. Claims 19 – 20, 22 – 23, 30 – 31, 33 – 38, 46 – 47, and 49 – 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown (U.S. Patent 5,849,290, of record).

This rejection is maintained for the reasons of record. Briefly, Brown teaches treatment of Parkinson's disease by administration of chelating agents, including instantly-elected desferrioxamine (see column 5 lines 31 – 33 for Brown's description that patients can be treated by administering desferrioxamine, and column 6 lines 40 – 44 which specifically states that

Parkinson's patients can be treated by "one or more of the above methods"). Brown also teaches that the doses to be administered are well-known in the art, and provides the artisan with prior art references which describe doses to be administered and also teaches that doses from 0.1 to 100 mg of agent per day are appropriate for an adult (see Brown, column 28 lines 10 – 20). Thus Brown teaches every element of claims 19 – 20, 22 – 23, and 35 – 38. The entire specification of Brown is on point to treatment of human patients, and therefore meets the limitation of claims 30 and 46. Claims 31 and 47 are rejected as the reference teaches desferrioxamine is suitable for treatment of patients with Parkinson's disease. Claims 33 and 49 are rejected because the method taught by Brown will necessarily reduce free iron levels in neural tissue, including brain tissue. Claims 34 and 50 are rejected as this method will reduce dopaminergic cell loss.

Applicant argues, on p. 7 of the remarks, that Brown does not teach administration to reduce the free iron levels in a neural tissue. Applicant also argues that anticipation by inherency requires that 1) the descriptive matter is "necessarily present" in the prior art and 2) that it would be so recognized by persons of ordinary skill in the art. Applicant also cites *Continental Can v Monsanto* in support of this argument. Applicant's arguments have been fully considered but they are not persuasive. With respect to 1) above, the inherent descriptive matter is in fact necessarily present in the reference by Brown. Brown teaches the doses to be used, both by providing a range suitable for small molecule chelators and by referring the artisan to other prior art publications, and Brown also teaches that desferrioxamine is a chelating agent. An agent is said to be a chelator when it binds to free metals. Brown teaches that Parkinson's disease is characterized by a death of dopaminergic nigrostriatal neurons, so treatment of the disease by administering a chelator would decrease levels of free metals in brain tissue. Thus the inherent matter is necessarily present, and a skilled artisan would recognize it as so.

Furthermore, applicant's argument that the artisan must necessarily recognize that the inherent feature necessarily be present is not persuasive. The case cited by applicant, Continental Can, was decided by the Federal Circuit in 1991. In 2003, the court rejected the reasoning now relied upon by applicant in *Schering Corp. v. Geneva Pharmaceuticals Inc.,* 67 USPQ2d 1664 (CAFC 2003). The court stated expressly that "At the outset, this court rejects the contention that inherent anticipation requires recognition in the prior art." Furthemore, the court very specifically addressed the Continental Can decision. The Schering court wrote:

> Contrary to Schering's contention, *Continental Can* does not stand for the proposition that an inherent feature of a prior art reference must be perceived as such by a person of ordinary skill in the art before the critical date. In *Continental Can*, this court vacated summary judgment of anticipation of claims reciting a plastic bottle with hollow ribs over a prior art reference disclosing a plastic bottle. The record contained conflicting expert testimony about whether the ribs of the prior art plastic bottle were solid. The accused infringer's expert testified that the prior art plastic bottle was made by blow molding, a process that would inherently produce hollow ribs. The patentee's experts testified that the prior art plastic bottle had solid ribs. The patentee disputed whether the blow molding inherently produced hollow ribs. Given the disputed material fact, this court vacated the summary judgment as improper. *Continental Can*, 948 F.2d at 1269. *Continental Can* makes no reference to whether the inherent feature, hollow ribs, was recognized before or after the critical date of the patent at issue. Read in context, *Continental Can* stands for the proposition that inherency, like anticipation itself, requires a determination of the meaning of the prior art. Thus, a court may consult artisans of ordinary skill to ascertain their understanding about subject matter disclosed by the prior art, including features inherent in the prior art. A court may resolve factual questions about the subject matter in the prior art by examining the reference through the eyes of a person of ordinary skill in the art, among other sources of evidence about the meaning of the prior art. Thus, in *Continental Can*, this court did not require past recognition of the inherent feature, but only allowed recourse to opinions of skilled artisans to determine the scope of the prior art reference. (underlines added)

Clearly the skilled artisan need not recognize every inherent feature of the invention at the time the invention is made. See also MPEP §2112(II), "An Inherent Feature Need Not Be Recognized at the Time of the Invention".

Applicant also argues that the teaching from Brown that chelators can be used for treatment of Parkinson's is optional and prophetic, and suggests that the teaching should not form the basis of a rejection under 35 USC 102. Applicant is directed to MPEP § 2123, particularly part I, entitled "Patents are Relevant as Prior Art for All They Contain". While the teaching of desforrioxamine for treatment of Parkisnon's may be described as optional, that does not matter. The reference teaches the invention now claimed.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 19 – 20, 22 – 23, 30 – 38, and 46 – 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown (US Patent 5,849,290) in view of Ben-Shachar (1991. Journal of Neurochemistry 56:1441 – 1444, of record).

The reasons why claims 19 – 20, 22 – 23, 30 – 31, 33 – 38, 46 – 47, and 49 – 50 are anticipated by Brown are set forth in the rejection under 35 USC 102 above. Briefly, Brown teaches administration of desferrioxamine to human patients for treatment of Parkinson's disease. However, Brown does not teach treating non-human mammals as recited in claims 32 and 48.

Ben-Schachar teaches prevention of neurodegenerative effects of 6-OHDA in non-human mammals as recited in claims 32 and 48 (specifcally rats), by prior administration of desferrioxamine. The reference teaches that administering 6-OHDA to rats is an animal model of Parkinson's disease (see p. 1441, first two paragraphs), and suggests that desferrioxamine could also be used in human patients to retard dopaminergic cell loss typical of Parkinson's disease. However Ben-Schachar does not teach administration of desferrioxamine to patients already having the disease.

It would have been obvious to one of ordinary skill in the art to modify the method from Brown to administer the chelators to non-human mammals instead of to humans. Brown teaches that the method is sufficient for treatment of Parkinson's disease in humans, whereas Ben-Schachar teaches that the same treatment is sufficient to protect against the neurodegenerative aspects of a rodent model of Parkinson's disease, and furthermore points out the similarities between the human and mouse forms of the disease.

Conclusion

6. No claim is allowed.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Daniel E. Kolker, Ph.D.
August 28, 2006

ROBERT C. HAYES, PH.D.
PRIMARY EXAMINER